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EXAMINER
TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
1651	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/856,717	Applicant(s) Asano et al.
	Examiner Christopher Tate	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 25, 2001*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-13 are presented for examination on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating viral and/or bacterial infections using the claimed mushroom extract, does not reasonably provide enablement for their prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated (and the prior art recognizes) that an extract of *Lentinus edodes* mycelium is useful in therapeutically treating numerous viral and/or bacterial infections. However, the claims encompass the use of such an extract to prevent any and all viral and bacterial infections which is clearly beyond the scope of the instantly disclosed invention (and the recognized state of the antimicrobial/antiviral art). Please note the term "prevention" is an absolute definition meaning to stop from occurring. Thus, the prevention of any and all viral and bacterial infections, many of which are not recognized in the art as being preventable (including HIV, ebola, dengue fever, St. Louis encephalitis, certain mycoplasma infections, superinfections by multiple-resistant bacteria including drug-resistant *Staphylococcus* and *Mycobacteria*, among many others) or at least not totally preventable, requires a higher standard for enablement (than does "treatment") which has not been met by the instant teachings.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 provides for the use of , but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Iizuka (US 4,629,627), Sugano et al. (US 4,461,760), or Ishida et al. (US 4,163,780).

A composition, including a pharmaceutical composition, comprising an extract of *Lentinus edodes* mycelium is claimed. Dependent claims include numerous intended forms and/or modes of administration thereof, as well as a method of treating a tumor or of preventing/treating a bacterial or viral infection via administering the composition.

Each of the cited references teach an anti-tumor pharmaceutical composition comprising an extract of *Lentinus edodes* mycelium as the active ingredient therein (the first reference further discloses that their extract composition also exhibits strong anti-viral activity), and the *in vivo* oral/nasal administration thereof (within a pharmaceutically acceptable carrier such as saline or water), wherein each of the reference extracts appear to be identical to the presently claimed

Lentinus edodes mycelium extract, since each of the extracts also expressly display anti-tumor (and for US '627 - anti-viral; and for US' 780 - anti-bacterial) activity, and/or were obtained in essentially the same manner as instantly disclosed - i.e., obtaining a freeze-dried powder from a culture medium comprising bagasse and rice bran, for example - using essentially the same steps as instantly disclosed (see, e.g., Example 1 on pages 13-14 of the instant specification) - see, e.g., US '627: col 3, line 12 - col 4, line 6 and col 6, line 25 - 10, line 29; US ' 760: col 1, line 65 - col 3, line 15, and col 4, line 44 - col 6, line 32; US ' 780: col 1, lines 25-55, col 5, lines 15-32, and Experimental Examples).

In the alternative, even if the claimed *Lentinus edodes* mycelium extracts are not identical to the referenced *Lentinus edodes* mycelium extract with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced *Lentinus edodes* mycelium extracts are likely to intrinsically possess the same characteristics of the claimed *Lentinus edodes* mycelium extract particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Please note that for those references that do not expressly teach anti-viral or anti-bacterial activity, the *in vivo* administration thereof, as disclosed by each of the cited references - e.g., to treat tumors - would inherently prevent such viral and/or bacterial diseases and, thus, also reads on the instantly claimed method of claim 12. Further, please note that the intended use (including intended mode of administration) of the claimed composition does

not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (i.e., nothing would preclude the reference saline/water compositions from being orally administered, e.g., in the form of a food/feed or drink, or from being injected or percutaneously absorbed). In addition, the underlying functional mechanism by which the anti-tumor, anti-viral, and/or anti-bacterial activity occurs (i.e., γδT cell activity) is not deemed to lend patentable distinction to the instantly claimed invention since such underlying functional activity would necessarily be intrinsic to the reference bioactive *Lentinus edodes* mycelium extracts. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by each of the cited references, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 1-11 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Iizuka et al. (EP 0,292,601) or Koga et al. (US 5,283,239).

Each of the cited references teach an anti-viral pharmaceutical composition comprising an extract of *Lentinus edodes* mycelium as the active ingredient therein, and the *in vivo* oral administration thereof (EP '601) or that it is used for oral or topical *in vivo* administration thereof (US '239) within a pharmaceutically acceptable carrier (such as saline, water, or ointment), wherein each of the reference extracts appear to be identical to the presently claimed *Lentinus edodes* mycelium extract, since each of the extracts also expressly display anti-viral activity, and were obtained in essentially the same manner as instantly disclosed - i.e., obtaining a freeze-dried powder from a culture medium comprising bagasse and rice bran, for example - using essentially the same steps as instantly disclosed (see, e.g., Example 1 on pages 13-14 of the instant specification) - see, e.g., EP '601: abstract, page 4, lines 1-43, page 5, line 36 - page 8, line 49, and claims; US '239: col 1, line 57 - col 2, line 35, col 6, line 34 - 42).

In the alternative, even if the claimed *Lentinus edodes* mycelium extracts are not identical to the referenced *Lentinus edodes* mycelium extract with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced *Lentinus edodes* mycelium extracts are likely to intrinsically possess the same characteristics of the claimed *Lentinus edodes* mycelium extract

particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, please note that the intended use (including intended mode of administration) of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (i.e., nothing would preclude the reference saline/water compositions from being orally administered, e.g., in the form of a food/feed or drink, or from being injected or percutaneously absorbed). In addition, the underlying functional mechanism by which the anti-tumor, anti-viral, and/or anti-bacterial activity occurs (i.e., γδT cell activity) is not deemed to lend patentable distinction to the instantly claimed invention since such underlying functional activity would necessarily be intrinsic to the reference bioactive *Lentinus edodes* mycelium extracts. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by each of the cited references, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iizuka (US 4,629,627), Sugano et al. (US 4,461,760), Ishida et al. (US 4,163,780), Iizuka et al. (EP 0,292,601), and Koga et al. (US 5,283,239).

The references are relied upon for the reasons discussed *supra*.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer one or more of the reference bioactive *Lentinus edodes* mycelium extract compositions to effectively treat a tumor, viral infection, and/or bacterial infection in a subject based upon the beneficial teachings provided by the cited references with respect to similar *Lentinus edodes* mycelium extract compositions displaying one or more of these activities. The adjustment of particular conventional working conditions (e.g., incorporating such *Lentinus edodes* mycelium extracts within a food, drink, or other commonly employed delivery and/or pharmaceutical vehicle), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1651 is (703) 308-4242.

Christopher R. Tate

Primary Examiner, Group 1651